STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

March 15, 2019

Micheal Ivy, MD, CEO
Bridgeport Hospital
267 Grant Street
Bridgeport, CT 06610

Dear Dr. Ivy:

Unannounced visits were made to Bridgeport Hospital that concluded on February 11, 2019 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations with additional information received through February 11, 2019.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by March 29, 2019

The plan of correction shall include:
(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
(2) the date each such corrective measure or change by the institution is effective;
(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by March 29, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

DATE(S) OF VISIT: February 11, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

We do not anticipate making any practitioner referrals at this time.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Heidi Caron, MSN, RN, BC, CLNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

HAC:mb

Complaint #24556, #24772

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

1. Based on medical record review, review of facility documentation, interviews, and policies, for

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three of ten patients who had histology testing performed, (Patient #1, Patient #2, and Patient #3), the facility failed to ensure that testing was performed properly to prevent cross contamination of specimens and/or failed to ensure polices/procedures were developed and/or implemented and/or that staff were trained and/or provided adequate supervision to ensure quality services in the subspecialty of histopathology. As a result of the system failure, Patient #1 received a hysterectomy on 12/28/18 based on a slide that was contaminated with pathological material from another patient (Patient #2).
During the onsite visit on 2/11/19, it was verified that the hospital had not performed histopathology since 1/25/19 in accordance with thier allegation of compliance and as a result, immediate jeopardy was abated. The findings include:

a. Patient #1 had a Hysteroscopy procedure on 12/3/18 with a biopsy obtained and was sent to pathology. Patient #1's pathology report dated 12/6/18 identified endocervical and endometrial curettings were positive for fragments of high grade serous carcinoma. On 12/28/18, Patient #1 had a robotic assisted total hysterectomy, bilateral salpingo-oophorectomy at Hospital #2. Review of the pathology report dated 12/28/18 of the gynecological tissue and lymph nodes removed during Patient #1's surgery identified no significant abnormality and/or benign lymph nodes. Further review identified that the error was discovered when Patient #1 had a hysterectomy on 12/28/18 at Hospital #2 when the tissue from the hysterectomy was examined and no tumor was identified. Hospital #2 re-examined Hospital #1's original histopathology slides and determined the tumor was present, therefore it was either entirely removed when the original specimens were collected or the specimens were mixed up or contaminated.
Patient #2 had an Endometrial biopsy on 12/3/18. Review of the pathology report dated 12/7/18 identified serous carcinoma of the uterus and cervix. Review of the operative report dated 12/18/18 identified that the patient underwent a robotic-assisted total hysterectomy.
Patient #3 had a blue light cystourethroscopy on 12/3/18. Review of the pathology report dated 12/7/18 identified that two floater cells of serous carcinoma gynecological tissue were noted and considered contaminated.
Review of facility documentation dated 12/4/18 indicated that Patient #2's tissue sample was embedded (Embedding is the process in which the tissues or the specimens are enclosed in a mass of the embedding medium using a mold), Patient #3's tissue sample was embedded next and Patient #1's tissue sample was embedded lastly with the use of forceps and tampers (unique tools for flattening tissue sections in an embedding mold).
Review of the Department Chair Meeting minutes dated 1/17/19, indicated that on 12/28/18, a patient (Patient #1) received a hysterectomy based on a slide contamination later determined to be pathologic material from another patient (Patient #2). Review of the office notes from Patient #1's gynecological physician dated 1/18/19 noted that Patient #1 and the patient's husband were informed of the pathology lab error.
Review of the hospital proximity report from CoPath (laboratory information system) identified that on 12/4/18, the specimens that were embedded at the same time revealed that another case, Patient #2, was identified with serous carcinoma. Patient #2's case was embedded first and the middle case between Patient #1 and Patient #2 was a bladder biopsy (Patient #3). Patient #3's slide was re-examined and it was determined a small piece of

serous cancer was present on the periphery of the slide and had no bearing on the final diagnosis for Patient #3.

Review of the genotyping done on Patient #1's original specimens determined the serous cancer was not that of Patient #1, but that of Patient #2. Patient #2's follow-up hysterectomy yielded a diagnosis of serous cancer. Further review identified that when it was determined specimens were contaminated, Hospital #1 ceased processing of surgical pathology specimens (exception of frozen sections) on 1/11/19.

Review of the Root Cause Analysis which began on 1/16/19 determined the tamper used at embedding was most likely the cause of the cross contamination.

Interview with Hystotechnologist #1 on 1/22/19 at 11:36 AM identified that s/he utilized forceps and tampers to imbed the tissues of Patient #1, Patient #2 and Patient #3 on 12/4/18. Hystotechnologist #1 indicated that although it was his/her practice to wipe off forceps and tampers prior to embedding the next patient's tissue, tissue could have been left on the tamper or the hot imbedding plate.

Additional interview with Histotechnologist #1 on 1/24/19 at 1:30 PM indicated that tampers are kept on the heating block/plate and if a tamper is used, it is placed on top of the specimen in the paraffin mold, then removed and placed back on the heating plate to melt the paraffin away and the bottom is wiped with a Kim-wipe between specimens. In addition, sometimes an embedder may need to press down to get the specimen on the same plate when using a tamper. Histotechnologist #1 further indicated that on 12/4/18 it was possible that some of the prior patient's specimen (Patient #2) went up the side of the tamper when she pressed the sample down onto the slide and only the specimen on the bottom came off when wiping resulting in the residual specimen carried over to the next two patients (Patient #1 and Patient #3).

Interview with the Laboratory Director on 1/22/19 at 9:56 AM identified that 2 of 3 patients had their tissue blocks cross contaminated during the tissue embedding process on 12/4/18 the Histotechnologist incorrectly utilized the tamper embedding tool which resulted in the cross contamination of paraffin embedded blocks. This resulted in an incorrect diagnosis of histopathology slides for Patient #1.

Interview with the Medical Director of the Laboratory on 1/22/19 at 10:50 AM noted that a "Kim-wipe is used to clean off each instrument in between patient use. Although the facility policy for routine embedding dated 7/2008 directed forceps are used and tissue tamps may be used to apply pressure and/or to exert an equal distribution force, the policy does not direct to wipe off after each patient use and directs to periodically wipe forceps and tampers during the embedding process to avoid carry-over from sample to sample 2.

b. Review of the hospital policy entitled "Embedding-Routine Embedding procedure" on 1/22/19 with the Histology Section Supervisor #1 identified that Procedure Step #8: "Using warmed forceps, apply gentle but equal pressure to the specimen so that it is flush against surface of mold, while moving the mold to a cooling area. There are tissue tamps that are available which have a larger surface area to exert an equal distribution of force ... Forceps and/or tampers should be wiped periodically during the embedding process to avoid carry-over from sample to sample." Further review failed to identify that a step by step procedure for proper use of 'tissue tamps' was not included and a step by step procedure for cleaning of forceps and/or tampers was not included.

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Review of the Policy entitled, "Maintaining Specimen Identity" procedure on 1/28/19 with the Histology Section Supervisor #1 revealed the policy did not address the use of tissue tampers. Review of the "Routine Embedding Procedure" on 1/22/19 identified that the proper use and cleaning of tissue tampers between specimens was not addressed.

c. Review of the personnel file for Histotechnologist #1 identified that she has been employed since May 12, 2008 and currently performs embedding, sectioning and staining of tissue specimens. The facility was unable to provide documentation that Histotechnologist #1 had embedding process training.

d. Review of the laboratory's organizational chart "Department of Pathology & Laboratory Medicine Organizational Chart (CLIA)" revealed the hospital had two General Supervisors for histopathology. Review of the two histopathology General Supervisor's credentials revealed the following educational qualifications:

i. Histopathology general supervisor #1 holds a Master of Science degree.

ii. Histopathology general supervisor #2 holds a Bachelor of Science degree.

Review of the CLIA regulation requirement directed that the General Supervisor should be a licensed physician certified in anatomic or clinical pathology.

The hospital failed to ensure the General Supervisors met the educational qualifications as stipulated in the CLIA regulations.

e. Review of the training documentation on 1/24/19 for 2 of 2 new grossing testing personnel identified that the initial training form is a "competency assessment form" for the 6 required elements and was reviewed and signed by the laboratory director. Further review identified that training documentation of the development of the knowledge and skill to perform macroscopic gross examination of tissue specimens was not available.

f. Review of personnel files for histology staff for 2017 and 2018 competency records on 1/23/19 revealed competency documentation for 9 of 9 personnel for the use of tissue tampers was not available.

g. Interview and review of hospital documentation with the histology section supervisor #1 on 1/23/19 at 10:45 AM identified that the laboratory's signed CMS 209 form revealed 23 general supervisors listed with no specialties indicated. Further review identified that the laboratory's CMS 116 form signed 1/28/19 revealed the specialty/subspecialty of pathology and histopathology with an annual volume of 49,491 tests. The hospital failed to document the specialties of each General Supervisor.

h. Interview with the Laboratory Director on 1/29/19 at 4:10 PM identified that Histology Lab Aide #1's (HLA#1) employee records on 1/23/19 indicated that the initial documentation of histology job competency verification for tissue embedding was signed by histology section supervisor #2 on 2/24/17. Further review identified that the verification form for the tissue embedding task states, "Reduces cross contamination of tissue from block to block ("floaters") by using clean molds and keeping work surfaces free of debris and excess paraffin, "however, the tissue tamper training documentation was not available.

Interview with HLA#1 on 1/23/19 at 1:05 PM identified that he/she was trained to embed tissue specimens in 2017 and was embedding in 2017 and throughout 2018.

i. Interview with the Histopathology Technical Supervisor on 1/24/19 at 11:35 AM identified that a Pathologist Assistant (PA#1) performed the training of the 2

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of 2 new grossing testing personnel. Further review identified that PA #1's training documentation was not available. Interview with the Grossing Testing Personnel #1 (GTP#1) on 1/28/19 at 3:40 PM identified that GTP#1 started grossing small biopsy specimens May 2017 and was trained by PA#1. Further review identified that training documentation was not available.